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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,384	10/29/2003	Mahesh Chaubal	IFT-5657A-1A1C6	8266

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BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/696,384	Applicant(s) CHAUBAL ET AL	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 12 May 2004, 17 June 2004, 02 November 2005, and 07 November 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* (U.S. Patent No. 5,133,908) in view of Cima *et al.* (U.S. Patent Application Publication No. US 2002/0048610)

The Stainmesse *et al.* patent teaches methods of producing nanoparticles comprising first, preparing a liquid phase consisting essentially of a solution of the substance in a solvent or in a mixture of solvents to which may be added one or more surfactants; second, preparing a second liquid phase consisting essentially of a non-solvent or a mixture of non-solvents for the substance and to which may be added one or more surfactants, the non-solvent or the mixture of non-solvents for the substance being miscible in all proportions with the solvent or the mixture of solvents for the substance; third, adding one of the liquid phases prepared in first or second step

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to the other with moderate stirring so as to produce a colloidal suspension of nanoparticles of the substance; and fourth, if desired, the removal of all or part of the solvent or the mixture of solvents for the substance and of the non-solvent or the mixture of non-solvents for the substance so as to produce a colloidal suspension of nanoparticles of the desired concentration or to produce a powder of nanoparticles (See Abstract; Column 2, Lines 32-52; and Claim 1). Various organic compounds may serve as the substance in the disclosed process, including polymers, waxes, biologically active substances, or pigments (See Column 2, Line 60 to Column 3, Line 38).

The Stainmesse *et al.* patent does not teach the use of seeds in the preparation of particles or of suspensions comprising such particles.

The Cima *et al.* publication discloses various method steps used to produce crystals of a particular substance possessing certain desired characteristics (See Abstract). Various components that assist in the disclosed methods are disclosed. The addition of non-solvents to influence the growth of crystals is disclosed (See Sections [0114] and [0115]). The use of various additives, such as surfactants, solvents, seed crystals, impurities, and other excipients is disclosed for the purpose of promoting or controlling nucleation and for influencing various crystal properties, such as crystal habit, polymorphic form, and particle size (See Sections [0014] to [0028], and [0119] to [0132]). The role of adjusting processing parameters for the purpose of influencing the product created by the disclosed methods is also disclosed. Such parameters include temperature, and its influence in altering the state of saturation; time, particularly its role in “ageing”; pH, and its role in determining the physical state and properties of the solid phase; and concentration, particularly the role of supersaturation in influencing the nucleation and

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growth rate of crystals. Various processing steps are also disclosed, including stirring, filtering, centrifuging, and the input of various types of energy, such as mechanical stimulation, ultrasound, and laser energy (See Sections [0182] to [0185] and [0188] to [0194]). The induction of nucleation by various process steps is disclosed, such as the input of energy, the addition of surfactants, and the alteration of the state of saturation. The induction of precipitation by various process steps is disclosed as well, including the addition of a non-solvent (See Sections [0201] to [0207]). Various analytical methods are also disclosed, including differential scanning calorimetry, or DSC (See Section [0266]). Various pharmaceuticals, suitable for the disclosed methods are also listed, itraconazole among them (See Section [0088], particularly Page 7, 1st Column, 4th Line).

It would be obvious to one of ordinary skill in the art to combine the teachings of Stainmesse *et al.* and Cima *et al.* into the objects of the instantly claimed invention. One of ordinary skill would be motivated to modify the disclosure of Stainmesse *et al.* in view of Cima *et al.* in order to gain greater control of product characteristics, including size and morphology. It is the position of the examiner that one of ordinary skill would be able to use the disclosure of the prior art to create suspensions and particles in accordance with the instantly claimed invention through routine experimentation, with a reasonable expectation of success. Thus, the instantly claimed invention is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-108 of U.S. Patent No. 6,607,784; Claims 1-99 of U.S. Patent No. 6,869,617; Claims 1-84 of U.S. Patent No. 6,951,656; and Claims 1-97 of U.S. Patent No. 6,884,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are substantially drawn to processes for preparing submicron-sized particles of an organic or pharmaceutical compound, which involves dissolving an organic compound in a water-miscible first solvent, mixing the resulting solution with a second solvent to define a pre-suspension, and adding energy to the mixture.

Claims 1-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed Claims 1-15 and 18-21 of copending Application No. 09/874,499 and Claims 1-108 of copending Application No. 10/246,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are substantially drawn to processes for preparing

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submicron-sized particles of an organic or pharmaceutical compound, which involves dissolving an organic compound in a water-miscible first solvent, mixing the resulting solution with a second solvent to define a pre-suspension, and adding energy to the mixture.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER